

EXHIBIT A

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NEUROVISION MEDICAL PRODUCTS, INC.

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO**

NEUROVISION MEDICAL PRODUCTS,
INC., a Missouri Corporation,

Plaintiff,

NUVASCHE, INC., a Delaware Corporation;
and DOES 1 through 20, inclusive.

Defendants.

Case No. 37-2014-00009821-CU-BT-CTL

CIVIL PROCEDURE CODE § 2019.210 DISCLOSURE

Plaintiff Neurovision Medical Products, Inc. (“Neurovision”) submits the following disclosure pursuant to Civil Procedure Code § 2019.210, as follows:

The trade secrets claimed by Neurovision in the present action are identified as follows:

1. The conductive ink-printed endotracheal tube prototype that Neurovision provided to NuVasive in or about January 2009.

2. The Technical Brief Neurovision provided to NuVasive in or about

1 December 2008. A true and correct copy of the Technical Brief is attached hereto as Exhibit 1.

2 3. Claims 1 through 7, as set forth in Patent No. US 8467,844 B2. A true and
3 correct copy of Patent No. US 8467,844 B2 is attached hereto as Exhibit 2.

4 4. Claims 1 through 19, as set forth in Patent No. US 8,634,894 B2. A true
5 and correct copy of Patent No. US 8,634,894 B2 is attached hereto as Exhibit 3.

6 Dated: November 12, 2014

LOWTHORP RICHARDS McMILLAN
MILLER & TEMPLEMAN

7 By:

8 9 DARIN MARX, Attorneys for Plaintiff
10 NEUROVISION MEDICAL PRODUCTS,
11 INC.

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ATTORNEYS AT LAW
VENTURA COUNTY

EXHIBIT 1

Technical Brief – Conductive Ink-Printed Endotracheal Tube

This Brief relates to electrodes for laryngeal electromyography and in particular to an electrode that is borne by the endotracheal tube, the tube commonly used during anesthesia and also during intensive care in order to support respiration of a human patient who is unable to breathe for themselves.

Background

Laryngeal surface electrodes on the endotracheal tube are currently used in various surgical procedures to provide monitoring of the electromyographic signals from the muscles of the vocal cords, or larynx. This type of monitoring allows the surgeon to intermittently stimulate the nerves to the vocal cord muscles with a nerve stimulator, and to electronically evaluate, or view on a video monitor, the muscle electrical responses, thereby giving the surgeon an indication of the location and physiologic integrity of these nerves during completion of the surgical task. This is particularly useful in Thyroidecotomy and Parathyroidectomy operations. In addition, laryngeal monitoring has been found to be of clinical value in certain neurosurgical and orthopaedic surgical procedures such as Anterior Cervical Diskectomy and Posterior Fossa Craniotomy. Also, with prolonged intubation and airway ventilator support, such as is provided in an intensive care unit for certain medical conditions, such as chest trauma, pneumonia, or chronic lung disease, medical practitioners would benefit from being able to evaluate laryngeal electromyography on an ongoing basis to evaluate the depth of sedation and the patient's suitability for ending airway support and removing the endotracheal tube.

Description of the Innovation

What is described here is an otherwise standard ET tube but with a permanent ink-printed surface coating of conventional, medical grade, electrically-conductive material, e.g., silver/silver chloride. This surface coating would embody the following: the electrode surfaces in contact with the vocal cords; the printed “electrical leads” to carry the electrical signals; and electrical contact pads near the termination of the ET tube, where electrical lead wires are attached (there are several common techniques to accomplish attachment of such external lead wires, including surface-to-surface, intimate electrical contacts, and needle-type electrical penetrators; both of these contact methods would be radially constrained, e.g., by a circumferential heat shrink “band” to assure appropriate electrical contact.). Further, an electrically insulating ink “overcoat” which would be printed over the above -listed printed electrical leads.

The above-described printed ET tube would incorporate lead wires as permanently attached (i.e., attached during production, primarily for the convenience of not attaching lead wires to the ET tube in the operating room). Alternately, the external lead wires could be secured, at the time of surgery, to the above-noted surface contact pads, via various, common methods. In any case, the external lead wires would terminate (at their other ends) in standard (DIN) medical connectors for (temporary) attachment to nerve monitoring equipment.

The electrically conductive coating and the electrically insulating "overcoat" coating are thin enough, tenacious enough, and flexible enough to withstand any envisioned, normal flexing of the ET tube without the coating "flaking" off of the ET tube. The (conductive and insulating) coatings would maintain integrity during use, including long-term intubation. Also, this design does not create a "zone of stiffness" (that does not allow the endotracheal tube to flex in its natural position, a semi S-curve, for the length of the electrode element), i.e., by constructing the part of the endotracheal tube electrode that is inside the patients mouth, pharynx, and larynx of components which are flexible, rather than rigid, the design of the endotracheal tube electrode can be optimized for signal collection and placement. Also, the electrode coatings are thin enough, with no discernable edge, such that they pose no source of injury or trauma to the vocal cords (or other tissues). Further, this design inherently eliminates the possible disassembly of "electrode components" (e.g., during long term intubation, thereby preventing traumatic injury to the vocal cords).

ET tubes, as described above, have successfully produced. All materials and processes utilized are conventional medical grade and are currently in use in medical products.

ET tubes, cuffed and uncuffed, with the above-described electrically conductive coating could be offered in several configurations, ranging from one contact area to several, however two and four (separate) contact areas are the most likely commercial product offerings. Also, the specific design of the contact areas could be easily varied.

Schematic of a Typical Configuration (without lead wires attached)

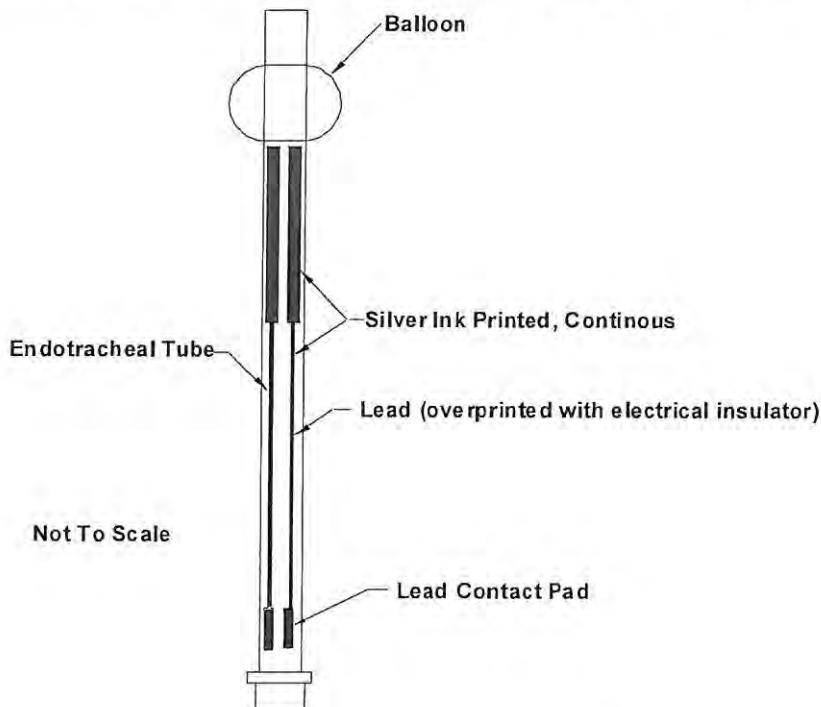


EXHIBIT 2



US008467844B2

(12) **United States Patent**
Rea et al.

(10) **Patent No.:** US 8,467,844 B2
(45) **Date of Patent:** Jun. 18, 2013

(54) **ELECTRODE FOR PROLONGED MONITORING OF LARYNGEAL ELECTROMYOGRAPHY**

(75) Inventors: **James Lee Rea**, Ventura, CA (US); **Stephen W. Blakely**, O'Fallon, MO (US)

(73) Assignee: **Neurovision Medical Products, Inc.**, Ventura, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 298 days.

(21) Appl. No.: 12/887,427

(22) Filed: Sep. 21, 2010

(65) **Prior Publication Data**

US 2011/0071379 A1 Mar. 24, 2011

Related U.S. Application Data

(60) Provisional application No. 61/244,402, filed on Sep. 21, 2009.

(51) **Int. Cl.**

H01R 43/00 (2006.01)

(52) **U.S. Cl.**

USPC 600/380; 600/393; 600/546; 29/825

(58) **Field of Classification Search**

USPC 600/380

See application file for complete search history.

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Primary Examiner — Lee S Cohen

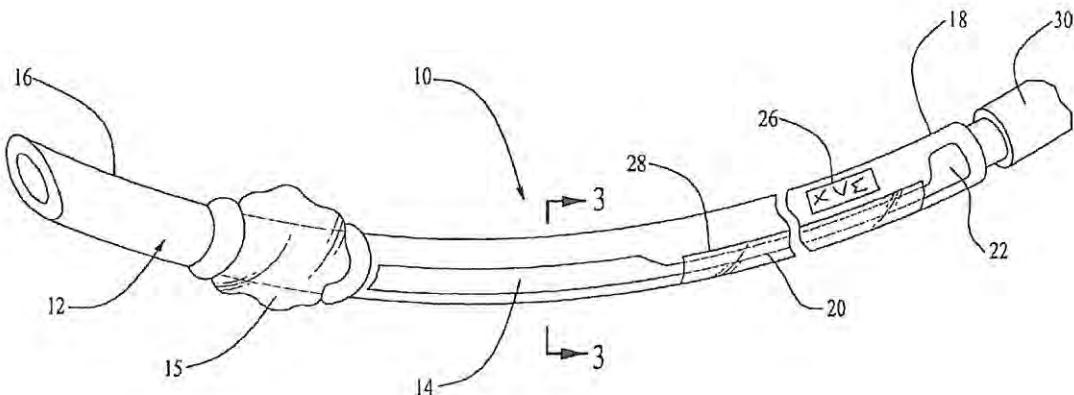
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ABSTRACT

Laryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals. Several embodiments of a laryngeal electromyography tube include a conductive electrode surface that is painted, screen printed or otherwise applied directly onto the body of an endotracheal tube, such that the final device has no raised surfaces which can injure the vocal cords. These endotracheal tube with integral laryngeal surface electrodes can be safely used placed for prolonged, continuous monitoring during surgery, after surgery and during intensive care treatment intubation without a need to remove and replace the tube at these various stages of treatment. In one embodiment, one electrode contacts the vocal cords and a second electrode contacts the tongue.

7 Claims, 6 Drawing Sheets



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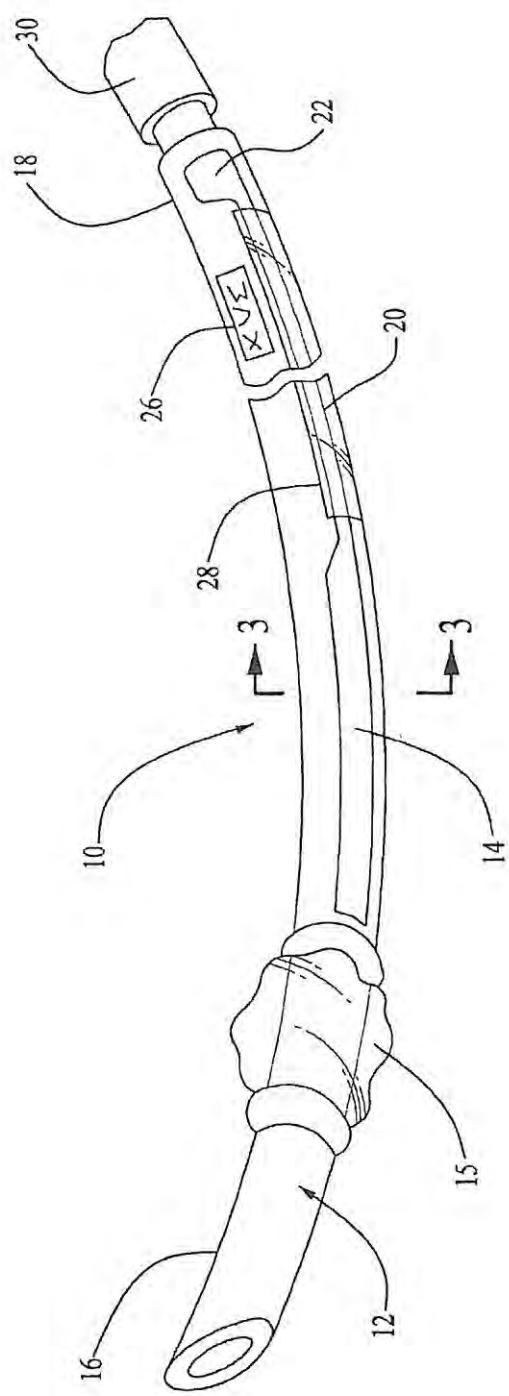
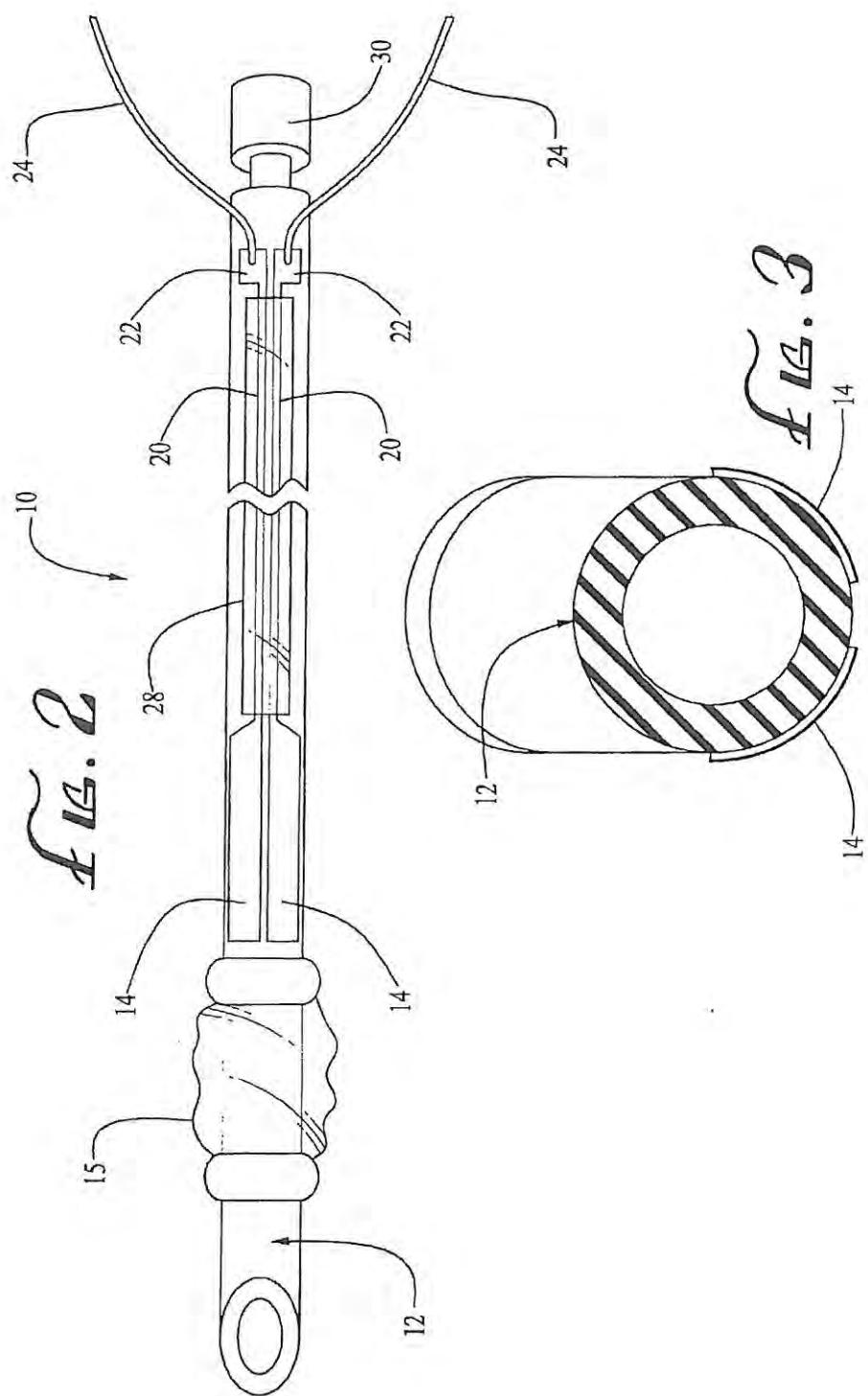
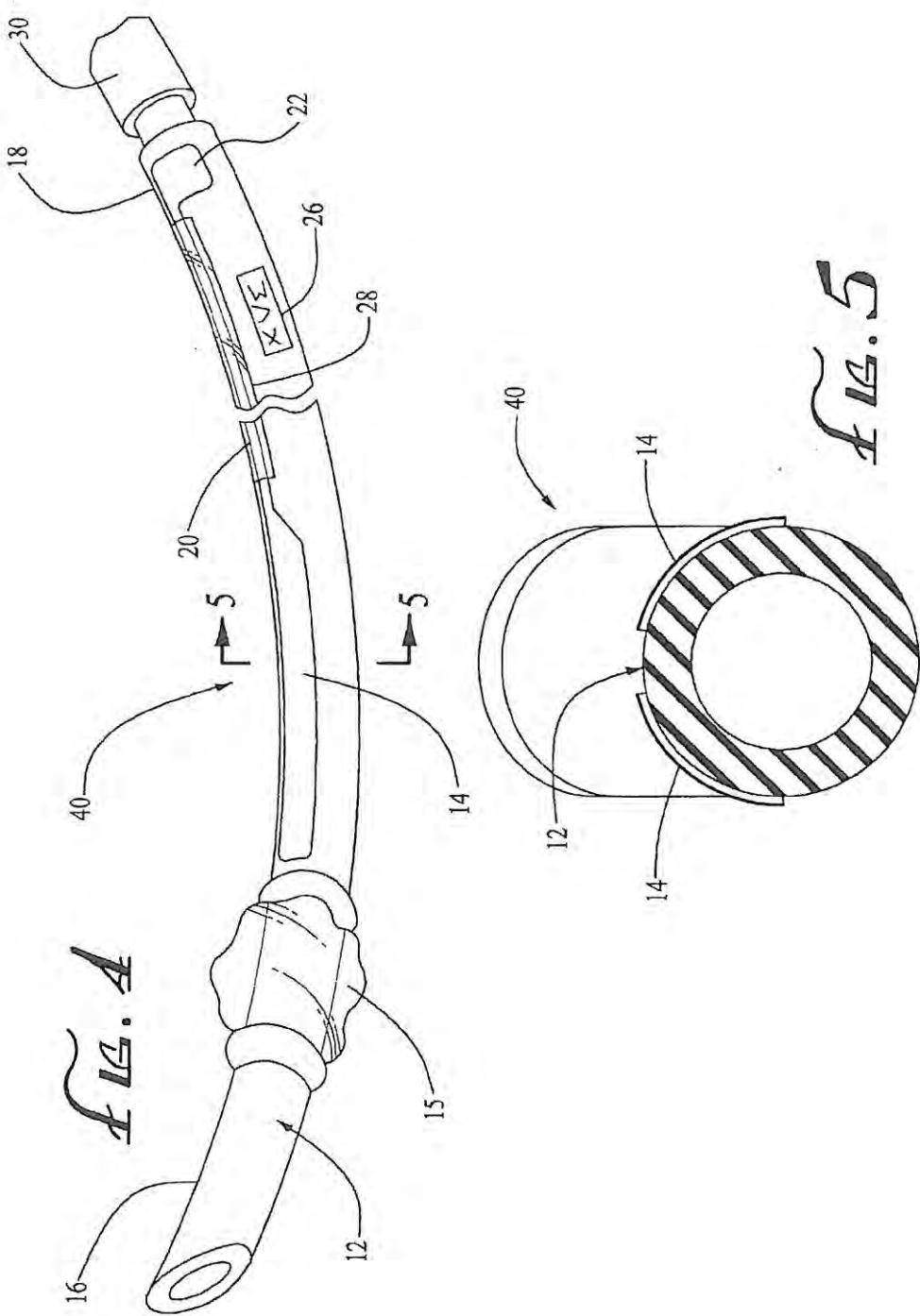
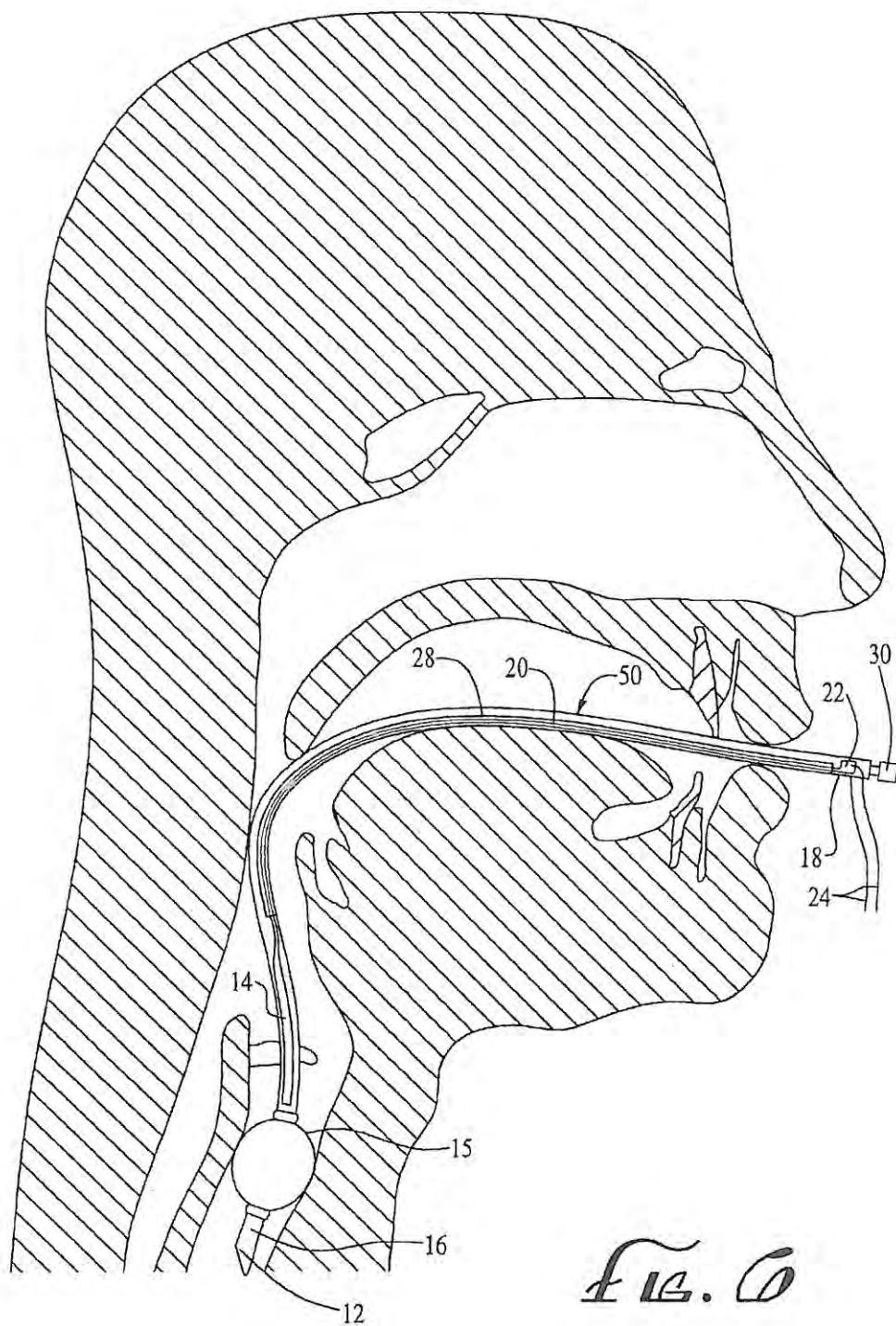


FIG. 1







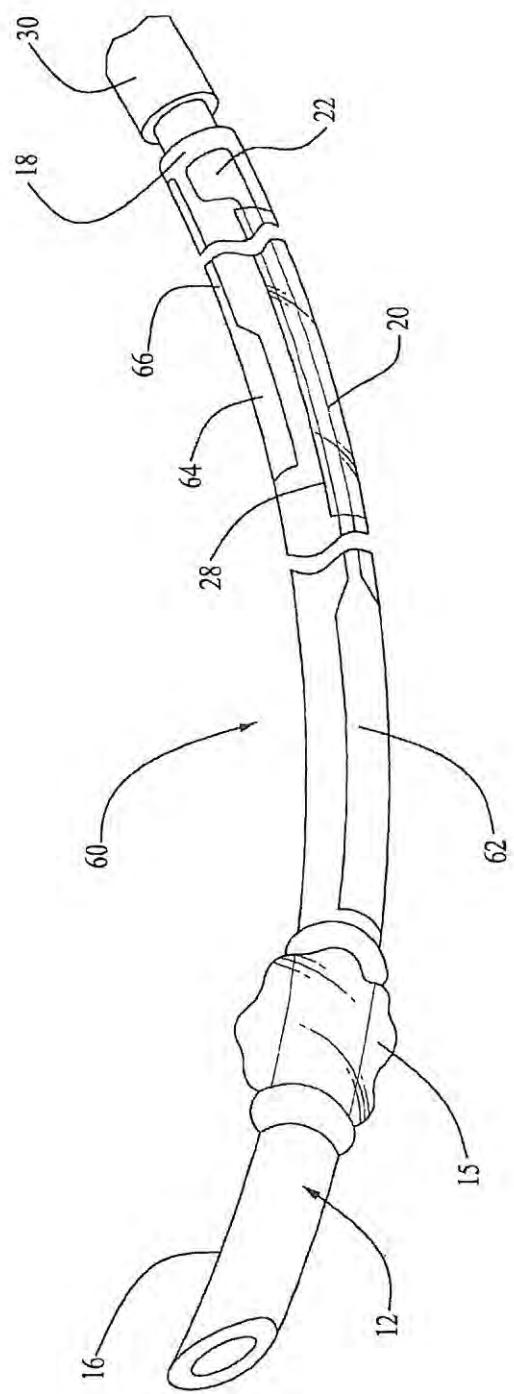


FIG. 7

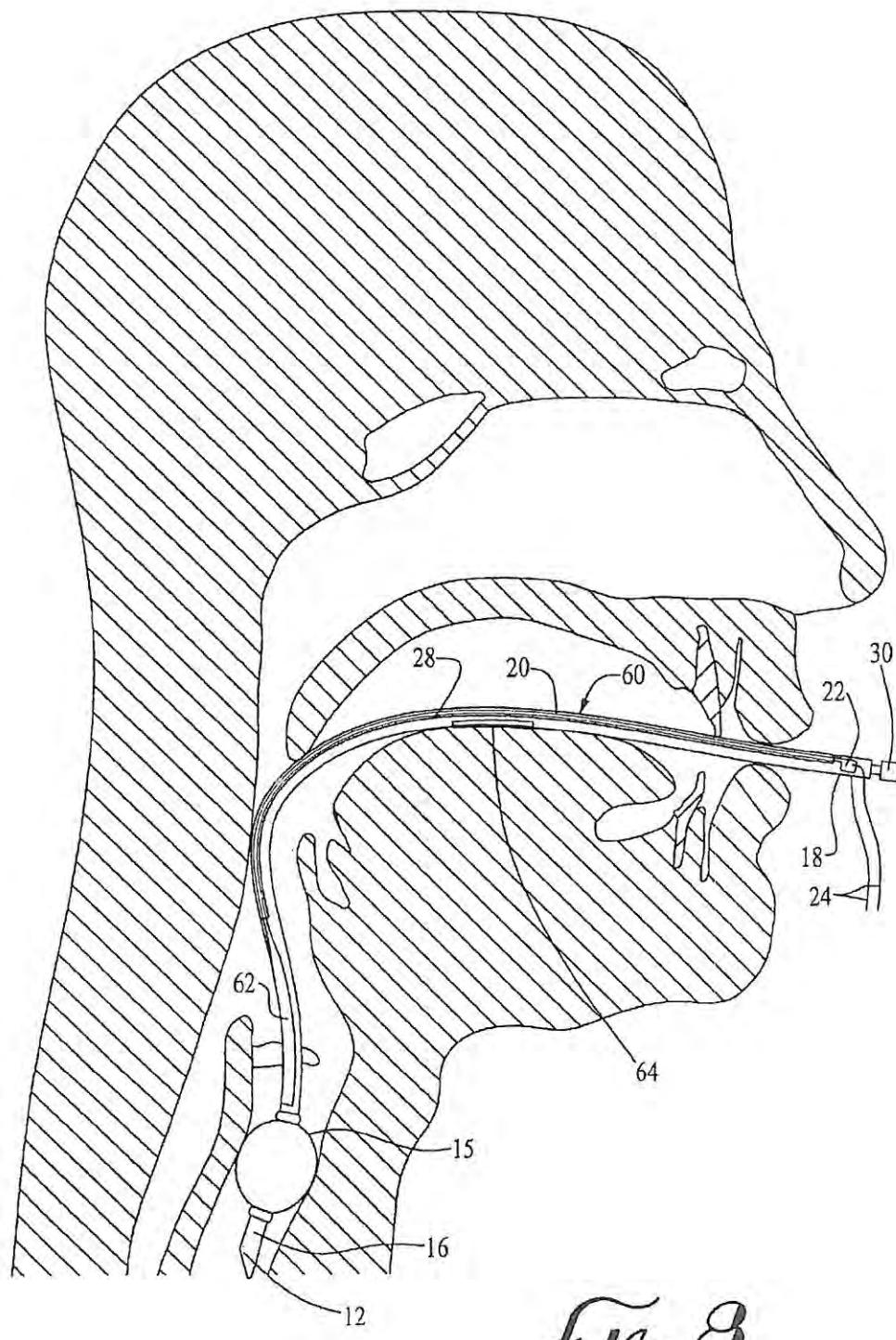


FIG. 8

**ELECTRODE FOR PROLONGED
MONITORING OF LARYNGEAL
ELECTROMYOGRAPHY**

This application claims benefit of U.S. Provisional Application Ser. No. 61/244,402, filed Sep. 21, 2009.

BACKGROUND

Endotracheal tubes are commonly used during anesthesia and intensive care in order to support respiration of a human patient who may be unable to breathe without the use of mechanical breathing support devices. Endotracheal tubes may have electrodes on the surface thereof for performing laryngeal electromyography and monitoring the recurrent laryngeal nerve during medical procedures. These electrodes on the endotracheal tube, referred to as laryngeal surface electrodes, are currently used in various surgical procedures to provide monitoring of the electromyographic signals from the muscles of the vocal cords, or larynx. The electrical signal typically transmitted to the tissue and detected using electronic monitoring equipment is generally from about 10 microvolts to about 2 millivolts. This monitoring procedure allows the surgeon to intermittently stimulate the nerves, for example nerves connected to the vocal cord muscles, with a nerve stimulator, and to electronically evaluate, or view on a video monitor, the muscle electrical responses, thereby giving the surgeon an indication of the location and physiologic integrity of these nerves during performance of a surgical procedure. This is particularly useful in Thyroidectomy and Para-thyroidectomy operations. In addition, laryngeal monitoring has been found to be of clinical value in certain neurosurgical and orthopedic surgical procedures such as Anterior Cervical Discectomy and Posterior Fossa Craniotomy. Also, with prolonged intubation and airway ventilator support, such as is provided in an intensive care unit for certain medical conditions, such as chest trauma, pneumonia, or chronic lung disease, medical practitioners would benefit from being able to evaluate laryngeal electromyography on an ongoing basis to evaluate the depth of sedation and the patient's status to determine if the airway support is still required or whether the endotracheal tube can be removed.

Currently, it is common practice to monitor laryngeal electromyography using laryngeal electrodes (the electrical signal pickup surfaces used to collect the muscle signals) which are either adhesively secured to the surface of the endotracheal tube or are embedded into the tube surface during the manufacture of the endotracheal tube. Both of these methods involve the addition of components to the endotracheal tube which are not commonly incorporated into this device such as metallic plates, adhesives, lead wires, and structural elements resulting in raised portions on the smooth physical profile of the endotracheal tube surface. Additionally, these devices can also introduce structures into the vicinity of the larynx and can cause injury to the vocal cords. For these reasons, the manufacturers of all currently available laryngeal surface electrodes do not recommend continuous laryngeal electrode placement for monitoring purposes in excess of eight hours. The surgeon and anesthesiologist are therefore required to remove the dedicated endotracheal tube with attached electrode and reintubate the patient with a standard, non-electrode endotracheal tube prior to moving the patient to the recovery room or ICU for prolonged respiratory support. This entails the risk of a separate, second airway manipulation and deprives the physician of valuable information which is provided by prolonged and continuous laryngeal monitoring.

Additionally, because the components of the electrodes in current embodiments of attachable or integrated endotracheal tube electrodes are different in structure and type to standard endotracheal tube components, they create a zone of stiffness that does not allow, or retards, flexing of the endotracheal tube when placed in its desired position, namely in a semi S-curve configuration extending for the length of the electrode element. By constructing the part of the endotracheal tube electrode that is inside the patients mouth, pharynx, and larynx using components which are flexible, rather than rigid, such as described herein below, the endotracheal tube electrode are located for optimal signal collection and minimal negative effects on the surrounding laryngeal tissue, subject to other constraints caused by the other materials used to form the laryngeal tube.

SUMMARY

An device for prolonged laryngeal electromyography monitoring comprises, in a preferred embodiment, an endotracheal tube, which can be a standard commercial endotracheal tube, with electrodes and electroleads screen printed on the exterior surface thereof using a conductive ink or paint, in a pattern such that it is optimized for positioning in the larynx and collection of electrical signals from the muscles and nerves comprising the vocal cords. The current most commonly used endotracheal tube is made of polyvinylchloride (PVC) or Silastic™. These tubes may also be imprinted with lettering to designate the manufacturer, size, serial number, scaled length to indicate depth of penetration from the lips, and other written precautions and information such that the manufacturer and regulatory agencies deem appropriate. As such the endotracheal tube laryngeal surface electrode incorporates imprinted patterns which provide conductive electrode plates on the surface without adding any additional structure or materials to the standard endotracheal tube other than the conductive ink or materials applied to the surface to form the electrodes. In a first embodiment the conductive paint or printing ink used consists of a liquid solution or suspension of conductive material, such as a silver, gold, silver chloride, or various other conductive materials, such that when the solution dries or otherwise solidifies it forms a firmly adherent, thin, electrically conductive layer on the body of the tube. In an alternative embodiment, the conductive material may sprayed on the tube surface in the desired pattern to form continuous conductive patterns on the surface.

An object is to provide a laryngeal surface electrode on an endotracheal tube where the electrode plates do not raise the profile of the body of the tube so as to create a safety hazard from possible trauma to the vocal cords.

Another object is to provide a laryngeal surface electrode that can be used for prolonged intubation and prolonged contact of the electrode surfaces with the vocal cords without raising concerns of unsafe condition or traumatic injury to the vocal cords resulting from separation or delamination of the electrode structure from the endotracheal tube surface.

Another object is to provide a laryngeal surface electrode that can remain indwelling during the entire surgical procedure and intensive care period of treatment of the patient, thereby providing the medical practitioner the ability to review laryngeal electromyography monitoring to assess the depth of sedation during treatment or surgery allowing the assessment of the patients laryngeal motor power during the decision process leading to removal of respirator support and of the endotracheal tube.

An additional object is to provide a PVC laryngeal surface electrode with the electrodes painted, printed or sprayed on

the surface thereof, thereby providing the flexibility of the PVC material throughout the length of the device. The painted, printed or sprayed on electrodes does not create a zone of stiffness anywhere along the length of the endotracheal tube, and particularly near the vocal cords. The flexibility of the endotracheal tube is not constrained or otherwise compromised by incorporation of a separate electrode structure on the tube surface. In addition, the traces, also referred to as leads are likewise applied to the surface of the tube, allowing the lead wires to be attached near the top of the tube (the external end of the endotracheal tube), and outside the patient's mouth, thus eliminating additional clutter in the patient's pharynx and an additional possible source of injury to the vocal cords with malpositioning of the device.

An additional object is to provide a laryngeal surface electrode that can be manufactured with electrode surfaces and multiple electrodes for various different applications and endotracheal tube sizes so as to provide a dual channel structure with four electrode plates or pediatric (single electrode) versions.

A further object is to provide an electrode that is economical to manufacture, efficient to use, and particularly well adapted for prolonged use. Other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a part of this specification and include exemplary embodiments and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 2 is a bottom view of the embodiment of FIG. 1.

FIG. 3 is a cross sectional view of the embodiment of FIG. 2 taken along line 3-3 of FIG. 2.

FIG. 4 is a perspective view of a second embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 5 is a top view of the embodiment of FIG. 4.

FIG. 6 is a view showing the endotracheal tube of FIG. 4 placed within the trachea with the electrode plates adjacent to the vocal cords.

FIG. 7 is a perspective view of a further embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 8 is a view showing the endotracheal tube of FIG. 7 placed within the trachea with one electrode plate adjacent to the vocal cords and one electrode contacting the tongue.

DETAILED DESCRIPTION

Certain features of the device described and shown herein are enlarged in the Figures for clarity and may be smaller and thinner than depicted in the Figures. In addition, other components, which may or may not be transparent, are shown as transparent so that the locations of the underlying features are readily visible.

With reference to FIGS. 1-3, a laryngeal electromyography tube 10 for use in prolonged laryngeal electromyography monitoring is shown. The laryngeal electromyography tube 10 comprises an endotracheal tube 12 upon which conductive electrode plates 14 are imprinted on the linear body of the tube 12 from a point adjacent to the endotracheal tube balloon

15, shown as a transparent material, at the distal end 16 of the tube 12. The length of the electrode plate 14 is chosen so as to be appropriate for clinical use and electrical signal capture. Extending away from the plates 14, toward the proximal end 18 of the laryngeal electromyography tube 10 is a conductive trace 20 which terminates on a conductive pad 22 for attachment of a lead wire 24. The lead wire 24 is of a length suitable to allow the laryngeal electromyography tube 10 to be attached to externally located electro-physiologic devices (not shown) such that the user may capture and evaluate the signals from the vocal cord received by the plates 14.

A typical endotracheal tube has a curved shape, such as an S-shape as shown in FIGS. 1-3 which typically is bent into an S-shape to match the anatomy of the throat. In FIGS. 1-3 the printed electrodes are shown on the outer curved surface for receiving electrical signals generated from nerves and muscles in the rear of the trachea. A second embodiment of the laryngeal electromyography tube 40 shown in FIGS. 4 and 5 has the electrodes placed on the concave (inner surface 20 of the curve) for picking up signals generated from the vocal cord located on the front surface of the trachea. FIG. 6 shows a third embodiment of a laryngeal electromyography tube 50 incorporating features of the invention. This embodiment incorporates the electrode plate 14 placement of FIGS. 1-3 with the conductive trace 20 running along the lower surface of the endotracheal tube, the portion of the trace 20 connecting to the plate 14 curving around the surface of the endotracheal tube so that the electrode plate 14 faces rearward to contact the vocal cords and the conductive trace 20 is on the lower surface of the tube as it passes through the mouth (i.e., facing the tongue). One skilled in the art will recognize that other electrode placements may be desired and it may in fact be desirable to have electrodes extending further around the circumference or even around the full 360° circumference of the tracheal tube.

Additional imprinting 26 for informational purposes is applied using nonconductive paint or printing ink is also seen on the body of the invention. An insulating covering 28, shown as a transparent material, is applied over the traces to protect against electrical shorting.

FIGS. 7 and 8 show a still further embodiment 60 which includes a single wide electrode 62 in contact with the vocal cords and a second electrode 64 which rests against the tongue as best shown in FIG. 8. In FIG. 7, a second conductive pad 22 connected to the trace 66 is not seen as it is on the backside of the endotracheal tube as viewed in FIG. 7.

A suitable conductive composition, referred to as an ink or paint, for forming the plates 14 and the traces 20 comprises a mixture of conductive materials, preferably metallic particles or metallic salts or oxides dissolved or suspended in a liquid carrier. Suitable conductive particles include, but are not limited to, finely divided particles or flakes of silver, silver salts such as silver chloride, silver oxide, gold, copper, copper chloride, platinum, carbon or graphite. The conductive materials are provided in the form of pellets, flakes, and nanoparticles. Silver is preferred because it is highly conductive (it has a resistivity of $1.62 \times 10^{-8} \Omega\text{m}$), is oxidatively stable and has the added advantage that its oxide is electrically conductive. Copper has a similar resistivity but its oxide acts as an insulator. The conductive materials are dissolved or suspended in a carrier which can be readily evaporated, leaving the conductive particles adhered to the surface of the endotracheal tube and in contact with adjacent particles to create a continuous conductive path from the electrode plate 14 along the length of the endotracheal tube to the conductive pad 22 and then to the lead wires 24. A typical ink comprises a mixture of the conductive material, which may include one or

more different materials such as silver in combination with silver chloride, in a liquid carrier, and may also include a binding agent or adhesion promoter. A typical ink for use on a polyvinyl chloride (PVC) endotracheal tube comprises 20-40% of a liquid carrier and 60-80% of a conductive material blend. For example a particular embodiment for use on PVC comprises 30% of a liquid carrier, such as dipropylene glycol methyl ether, 60% silver in the form of 50% silver flakes and 10% silver chloride, and a resin binder such as a modified polyester resin. Once the liquid carrier is removed, the printed electrode comprises about 85% conductive silver material (silver and silver chloride), the balance being the resin binder. Numerous suitable conductive inks are available from Creative Materials of Tyngsboro, Mass.

For use on a silicone endotracheal tube a preferred carrier liquid is Xylene. The ink typically has a viscosity in excess of 10,000 centipoises, preferably about 12,000-16,000 cps. One skilled in the art will recognize that numerous different carriers can be employed, preferably a liquid that does not attack or dissolve the polymeric material comprising the endotracheal tube and is readily evaporated. For example, other suitable liquid carriers include water, methanol, ethanol, isopropanol, 1-methoxypropanol, butanol, ethylhexyl alcohol, terpineol, ethylene glycol, glycerine, ethyl acetate, butyl acetate, methoxypropyl acetate, carbitol acetate, ethylcarbitol acetate, methylcellosolve, butylcellosolve, diethyl ether, tetrahydrofuran, dioxane, methyl ethyl ketone, acetone, dimethylformamide, 1-methyl-2-pyrrolidone, hexane, heptane, dodecane, paraffin oil, mineral spirit, benzene, toluene, 30 xylene, chloroform, methylene chloride, carbon tetrachloride, acetonitrile and dimethylsulfoxide. The viscosity should also be such that the ink once applied does not flow on the surface of the tube so that the dimensions of the printed or painted electrode can be held with design parameters as to 35 with ands thickness.

To apply the ink to the endotracheal tube the tube can first be wiped with a solvent to remove any oils or foreign materials on the surface. Care must be taken to select a cleaning solvent that is compatible with the polymeric material comprising the endotracheal tube and does not affect the surface of the tube. However, wiping the surface may not be necessary. In a first embodiment the conductive ink is applied using a brush, preferably in an automated manner to assure reproducibility. However, other techniques can be utilized such as 40 spraying or using a roller type applicator or other typical printing techniques. In a preferred embodiment the printed surface is subjected to an elevated temperature (35° C.-140° C.), preferably 100° C.-140° C. for several minutes to quickly evaporate the liquid carrier followed by 12-24 hours exposure 45 in clean environment at ambient temperature. The resultant device is an endotracheal tube with an electrode structure toward the distal end thereof and traces from the electrode structure to the proximal end permanently printed on the outer surface thereof, the traces being electrically insulated. 50 The printed electrode and traces are about 0.001 inches (25 microns) in thickness so that the diameter of the endotracheal tube is substantially unchanged and there are no extraneous intervening materials, such as is present when a stick-on electrode is used, which can lift up or present sharp edges.

A PVC endotracheal tube incorporating an electrode structure painted on the surface in the manner described above using the silver/silver chloride ink described above has been used in patients and provides consistent stimulation delivery (the average minimum current required for stimulation of the RLN is about 0.50 mA) and a measurably and consistent output comparable to current electrodes adhesively secured

on endotracheal tubes, such as the Dragonfly® stick-on laryngeal electrode supplied by Neurovision Medical, Inc.

Such a composition can be applied by various methods including but not limited to painting, screen printing, transfer printing, gravure, flexographic or offset printing, as well as inkjet or electrostatic printing methods. The conductive solutions preferably use rapidly evaporating solvents which may be provided with high concentrations of the conductive component and can in fact be provided as a solvent free composition. As an alternative, a polymer doped with conductive additives can be used. In a still further embodiment electrically conductive polymers can be used. Based on the teachings herein one skilled in the art will recognize that other conductive solutions or compositions can be utilized.

Preferred materials for construction of the endotracheal tube are PVC or a silicone polymer, such as Silastic®. However, based on the teachings herein one skilled in the art will recognize that numerous alternative materials may be used to construct the endotracheal tube 12. The non-conductive, insulating covering 28 is chosen to be compatible with the tube 12 material to minimize or eliminate the likelihood of delamination. For example, on a PVC endotracheal tube a PVC insulating covering 28 is preferred. For a silicone endotracheal tube, a silicone insulating covering 28 is preferred. While the device described herein is an endotracheal tube, one skilled in the art will also recognize that other medical devices, such as catheters can be prepared in the same manner to have electrodes on the surface thereof.

The endotracheal tube with imprinted electrode surfaces allows safe, long term intubation and clinical monitoring of human laryngeal electromyographic signals. Prior and currently available devices include structures on the surface of the tube which are raised and can have sharp edges and which can cause injury to the tissue of the throat, larynx and vocal cords. For these reasons, the manufacturers of all currently available laryngeal surface electrodes do not recommend continuous laryngeal electrode placement for monitoring purposes in excess of eight hours. The surgeon and anesthesiologist are therefore required to remove the dedicated endotracheal tube with attached electrode and reintubate the patient with a standard, non-electrode endotracheal tube prior to moving the patient to the recovery room or ICU for prolonged respiratory support. This entails the risk of a separate, second airway manipulation and deprives the physician of valuable information which is provided by prolonged and continuous laryngeal monitoring. Since the currently described device with electrical paths applied directly to the surface of the endotracheal tube are smooth, these hazards are eliminated. The described device can be placed prior to or at the time of the surgical procedure, and it can remain in position in the patient after the procedure (i.e., in the recovery room, ICU and subsequent prolonged respiratory support) with significantly reduced risks of injury to the patient. Intubations in excess of 8 hours and in fact for 24-48 hours (long term intubation) are therefore now possible.

Further, printing the electrode on the surface provides for optimization of the configuration of the electrode plates on the body of the endotracheal tube without introducing stiff attachments or physical additions. As a result no physical stress is placed on the tube that could inhibit easy placement of the tube in the trachea of a human patient.

While specific embodiments are disclosed herein, it is understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various forms. Specific structural and functional details described herein are not to be interpreted as limiting, but merely exemplary and are

a basis for teaching one skilled in the art to practice the invention claimed herein below.

The invention claimed is:

1. A device for use in monitoring electrical signals during laryngeal electromyography comprising:
 an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface one or more electrically conductive electrode plates applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrode plates,
 said tube having on its surface electrically conductive traces connected to or integral with the electrode plates, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal end thereof,
 conductive pads connected to or integral with the conductive traces, the pads applied directly to the tube surface at the proximal end of the endotracheal tube, and
 electrical leads connected to the pads, said leads adapted to connect to monitoring equipment,
 the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode plates to a point adjacent the conductive pads wherein a first of said electrode plates is located proximal of the balloon and positioned to contact the vocal cords when placed within the trachea and a second electrode plate is located further proximal thereof and positioned to contact the tongue when the first electrode plate is positioned to contact the vocal cords.
 2. The device of claim 1 wherein said electrically conductive electrode plates, traces and pads comprise a dried conductive paint or printing ink with a liquid carrier removed therefrom.
 3. The device of claim 1 wherein the surface of the conductive electrode plates are substantially flush with the outer surface of the endotracheal tube.

4. A method of forming an electrode bearing endotracheal tube for laryngeal electromyography comprising:
 providing an endotracheal tube having a retaining balloon at a distal end thereof,
 forming on an exterior surface of the endotracheal tube one or more electrode plates, at least one trace attached to each of the one or more electrode plates and a conductive pad attached to a proximal end of the traces, a first of said electrode plates located at the distal end of the endotracheal tube proximal of the retaining balloon, the conductive pad or pads located at a proximal end of the endotracheal tube,
 the electrode plates, traces and electrode pads formed by applying a conductive ink in a liquid carrier to the exterior surface of the endotracheal tube,
 evaporating the liquid carrier to provide an electrically conductive path from the electrode plates to the endotracheal tube proximal end, and
 forming an insulating barrier over the traces, the barrier extending from a point of connection of the traces to the electrode plates to a point of connection of the traces to the electrode pads
 wherein a second electrode plate is located proximal of said first electrode plate, the first electrode plate positioned to contact the vocal cords and the second electrode plate positioned to contact the tongue when properly positioned for performing laryngeal electromyography.
 5. The method of claim 4 wherein the conductive ink comprises electrically conductive particles in said liquid carrier.
 6. The method of claim 5 wherein electrically conductive particles comprise finely divided particles or flakes of silver, silver compounds including but not limited to silver chloride and silver oxide, gold, copper, copper chloride, platinum, carbon or graphite.
 7. The method of claim 5 wherein the conductive particles comprises at least about 60% of the ink.

* * * * *

EXHIBIT 3



US008634894B2

(12) **United States Patent**
Rea et al.(10) **Patent No.:** US 8,634,894 B2
(45) **Date of Patent:** *Jan. 21, 2014(54) **ELECTRODE FOR PROLONGED MONITORING OF LARYNGEAL ELECTROMYOGRAPHY**(71) **Applicant:** Neurovision Medical Products, Inc., Ventura, CA (US)(72) **Inventors:** James Lee Rea, Ventura, CA (US); Stephen W. Blakely, O'Fallon, MO (US)(73) **Assignee:** Neurovision Medical Products, Inc., Ventura, CA (US)(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) **Appl. No.:** 13/909,966(22) **Filed:** Jun. 4, 2013(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 61/244,402, filed on Sep. 21, 2009.

(51) **Int. Cl.**A61B 5/0492 (2006.01)
H01R 43/00 (2006.01)(52) **U.S. Cl.**

USPC 600/380; 600/393; 600/546; 29/825

(58) **Field of Classification Search**CPC A61B 5/0421; A61B 5/0492
USPC 600/380

See application file for complete search history.

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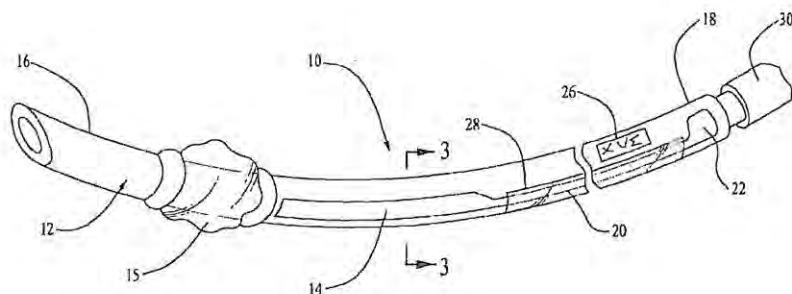
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Primary Examiner — Lee S Cohen(74) **Attorney, Agent, or Firm** — Koppel, Patrick, Heybl & Philpott; Michael J. Ram(57) **ABSTRACT**

Laryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals. Several embodiments of a laryngeal electromyography tube include a conductive electrode surface that is painted, screen printed or otherwise applied directly onto the body of an endotracheal tube, such that the final device has no raised surfaces which can injure the vocal cords. These endotracheal tube with integral laryngeal surface electrodes can be safely used placed for prolonged, continuous monitoring during surgery, after surgery and during intensive care treatment intubation without a need to remove and replace the tube at these various stages of treatment. In one embodiment, one electrode contacts the vocal cords and a second electrode contacts the tongue.

19 Claims, 6 Drawing Sheets

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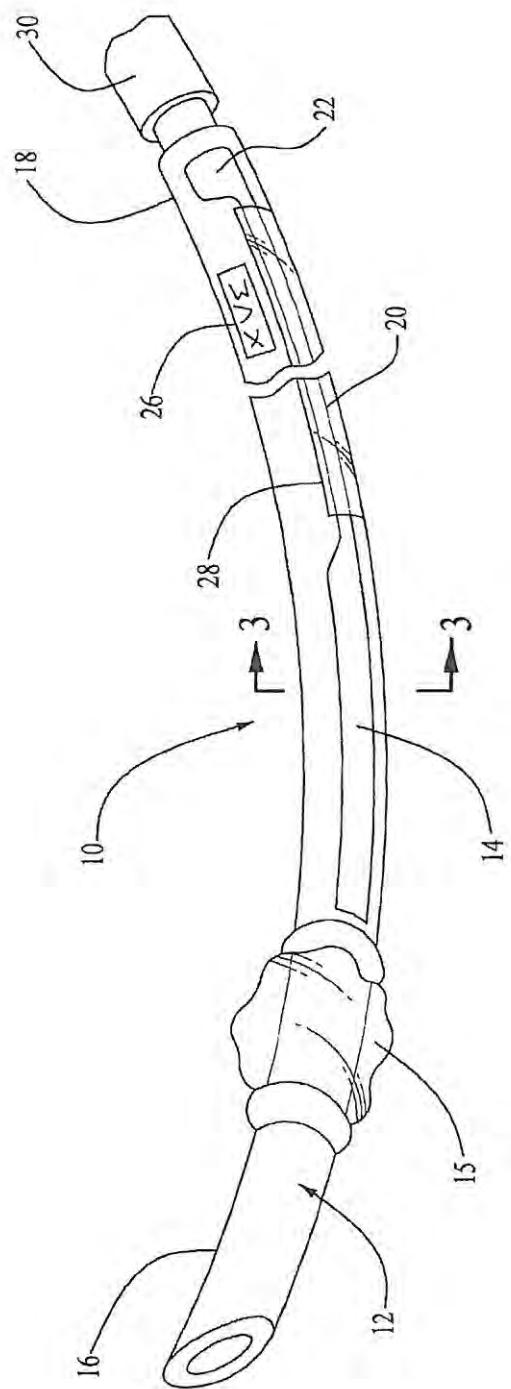
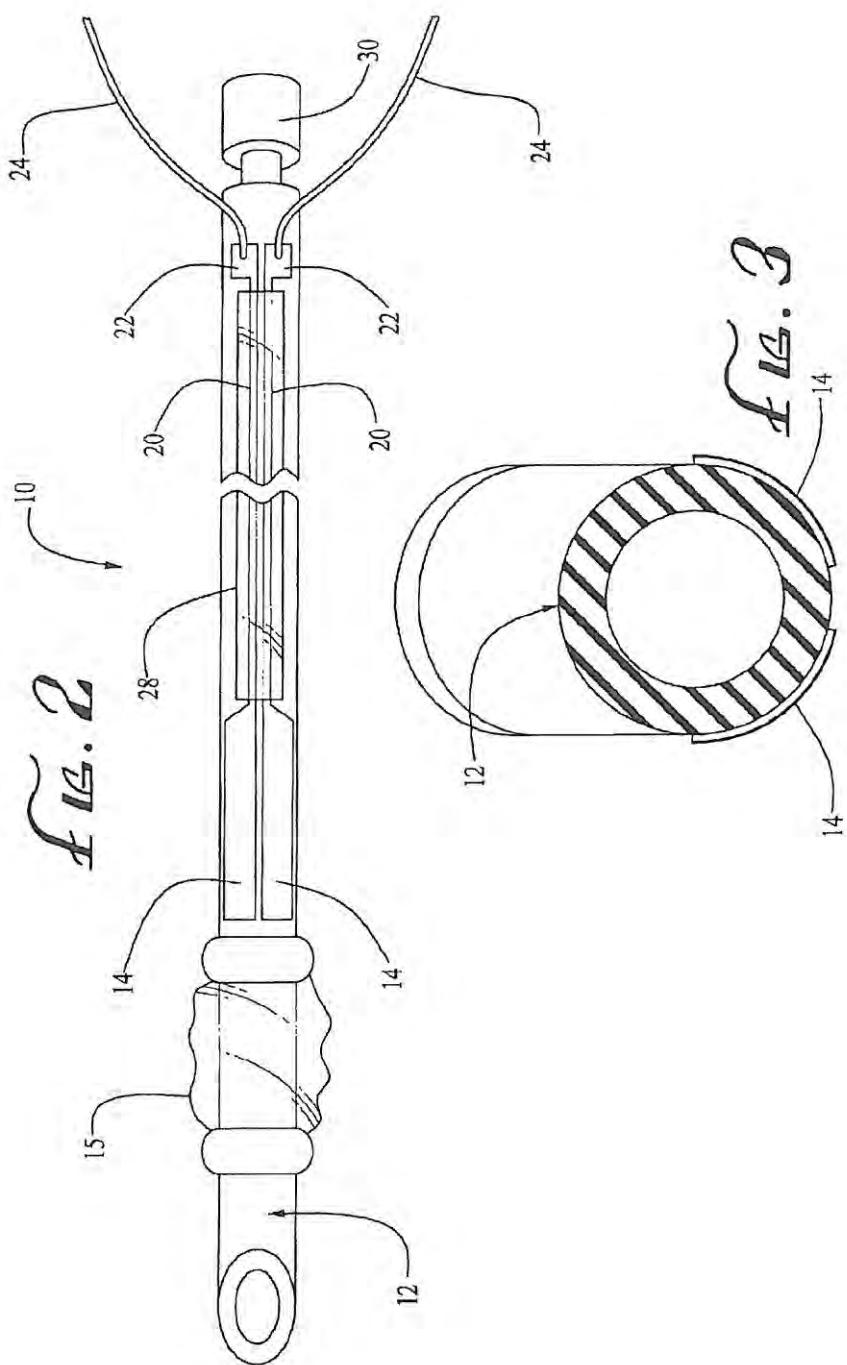
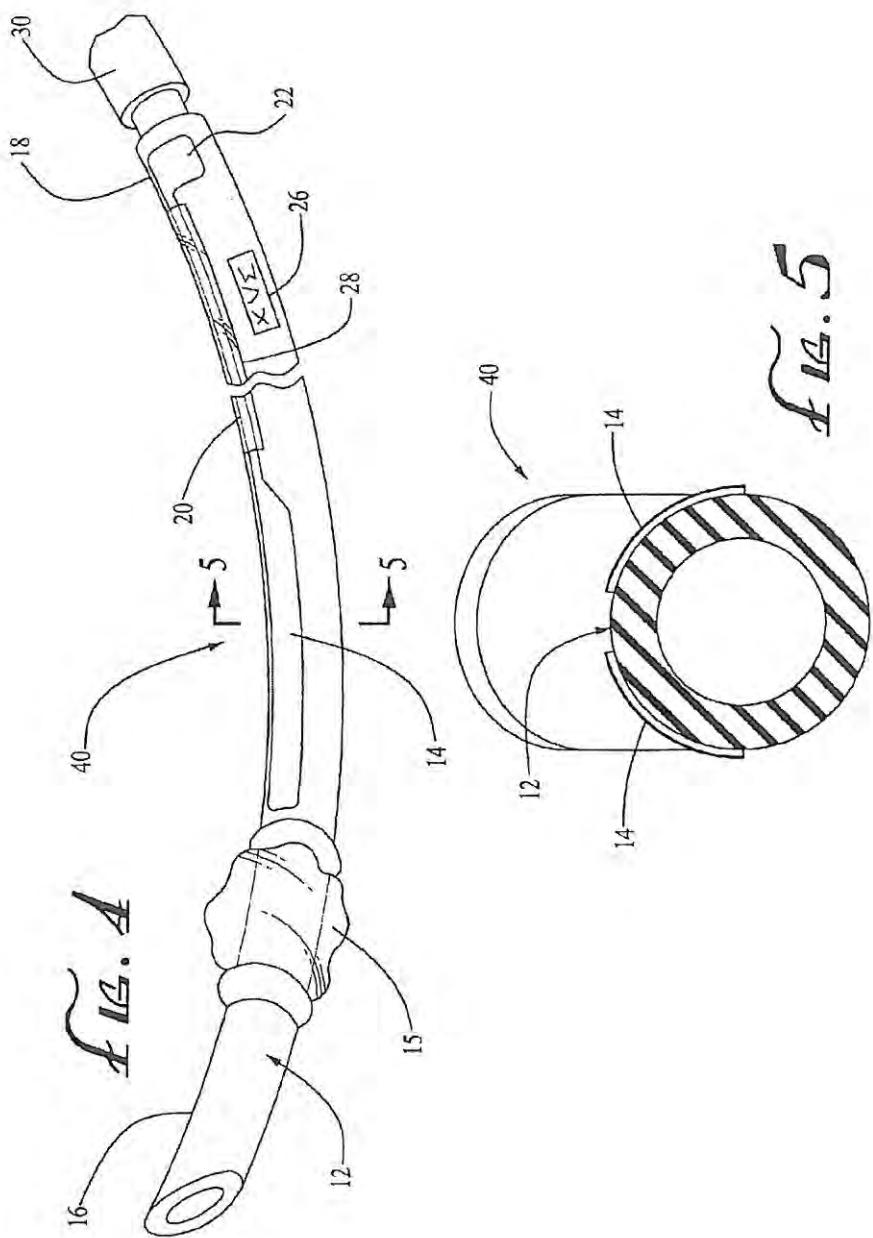
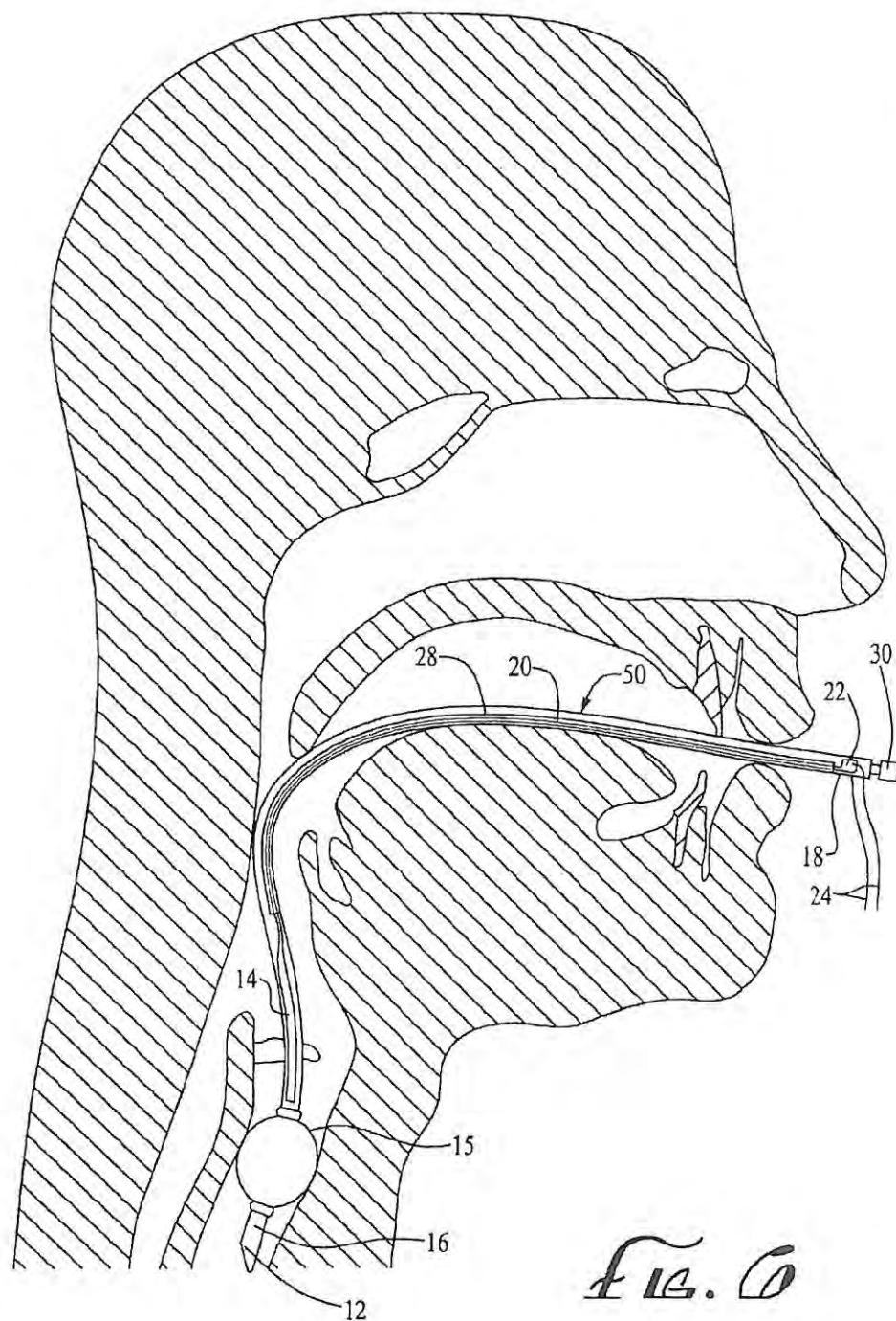


FIG. 1







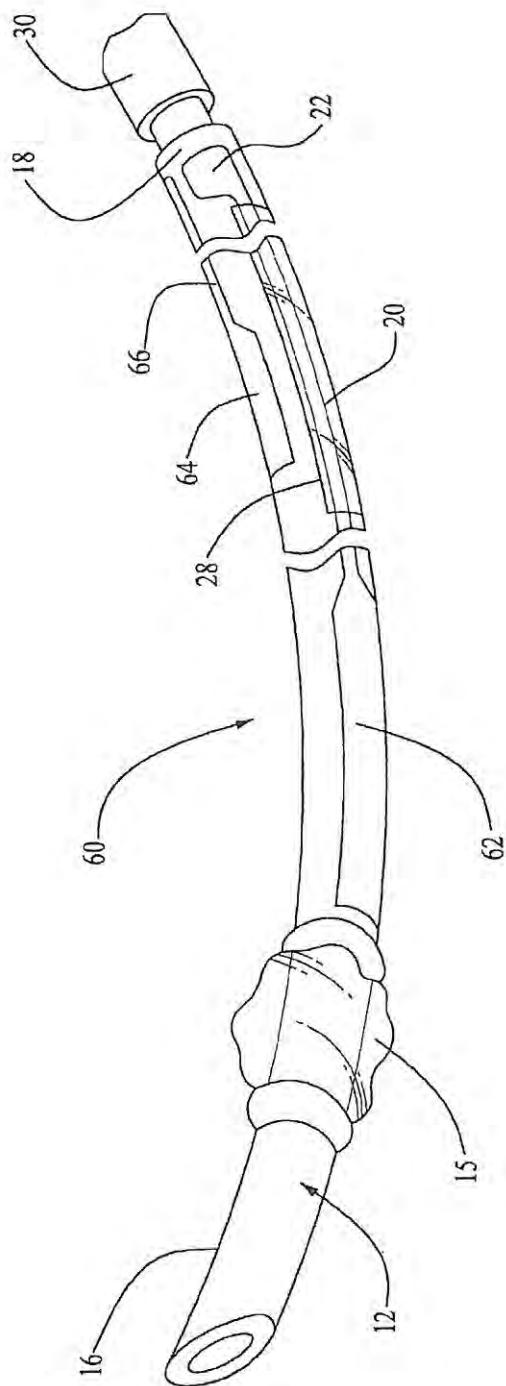
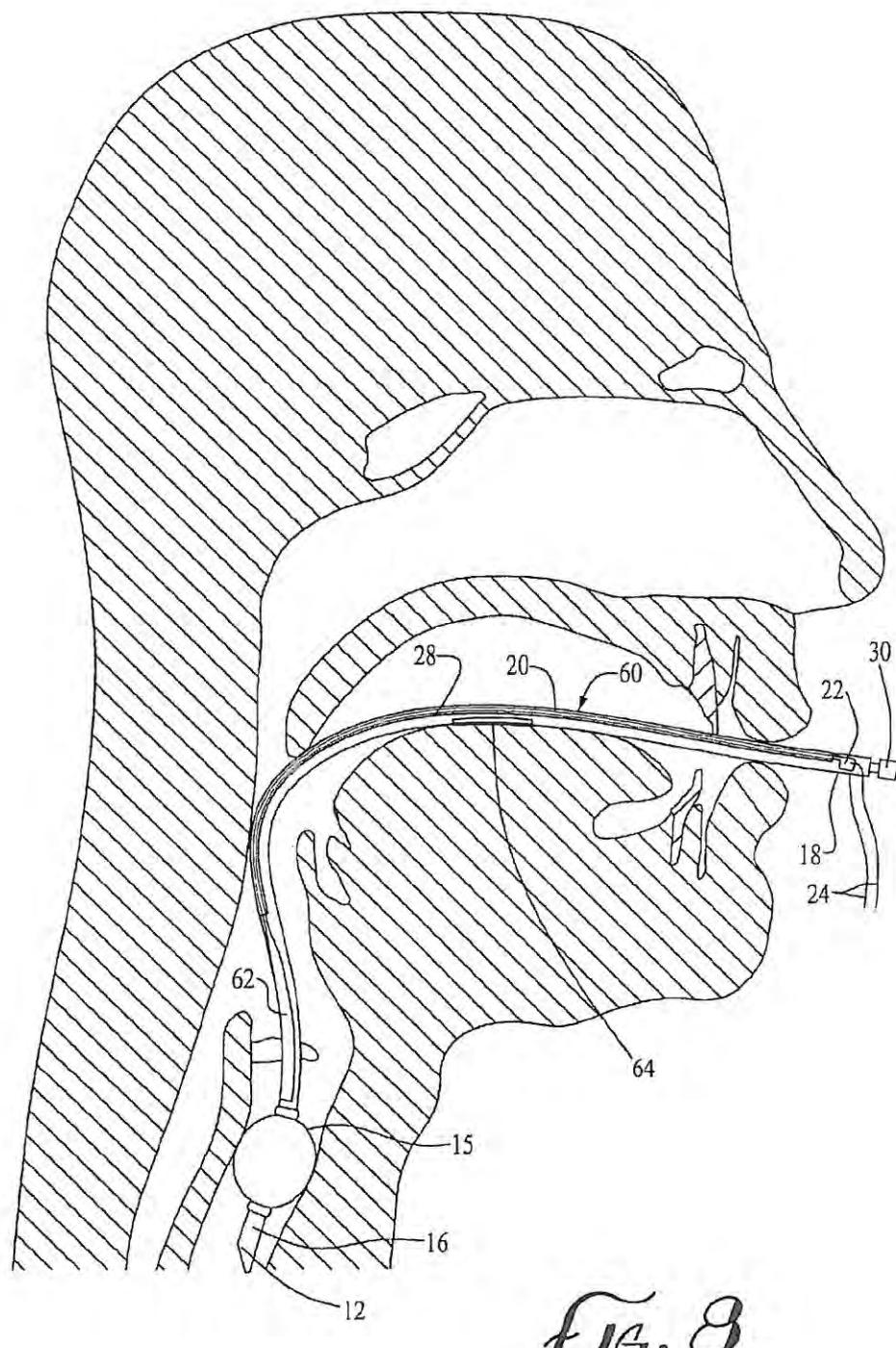


FIG. 7



ELECTRODE FOR PROLONGED MONITORING OF LARYNGEAL ELECTROMYOGRAPHY

This application is a Divisional of patent application Ser. No. 12/887,427, filed Sep. 21, 2010, now U.S. Pat. No. 8,467,844, issued Jun. 18, 2013, and claims benefit of U.S. Provisional Application Ser. No. 61/244,402, filed Sep. 21, 2009.

BACKGROUND

Endotracheal tubes are commonly used during anesthesia and intensive care in order to support respiration of a human patient who may be unable to breathe without the use of mechanical breathing support devices. Endotracheal tubes may have electrodes on the surface thereof for performing laryngeal electromyography and monitoring the recurrent laryngeal nerve during medical procedures. These electrodes on the endotracheal tube, referred to as laryngeal surface electrodes, are currently used in various surgical procedures to provide monitoring of the electromyographic signals from the muscles of the vocal cords, or larynx. The electrical signal typically transmitted to the tissue and detected using electronic monitoring equipment is generally from about 10 microvolts to about 2 millivolts. This monitoring procedure allows the surgeon to intermittently stimulate the nerves, for example nerves connected to the vocal cord muscles, with a nerve stimulator, and to electronically evaluate, or view on a video monitor, the muscle electrical responses, thereby giving the surgeon an indication of the location and physiologic integrity of these nerves during performance of a surgical procedure. This is particularly useful in Thyroidectomy and Para-thyroidectomy operations. In addition, laryngeal monitoring has been found to be of clinical value in certain neurosurgical and orthopedic surgical procedures such as Anterior Cervical Discectomy and Posterior Fossa Craniotomy. Also, with prolonged intubation and airway ventilator support, such as is provided in an intensive care unit for certain medical conditions, such as chest trauma, pneumonia, or chronic lung disease, medical practitioners would benefit from being able to evaluate laryngeal electromyography on an ongoing basis to evaluate the depth of sedation and the patient's status to determine if the airway support is still required or whether the endotracheal tube can be removed.

Currently, it is common practice to monitor laryngeal electromyography using laryngeal electrodes (the electrical signal pickup surfaces used to collect the muscle signals) which are either adhesively secured to the surface of the endotracheal tube or are embedded into the tube surface during the manufacture of the endotracheal tube. Both of these methods involve the addition of components to the endotracheal tube which are not commonly incorporated into this device such as metallic plates, adhesives, lead wires, and structural elements resulting in raised portions on the smooth physical profile of the endotracheal tube surface. Additionally, these devices can also introduce structures into the vicinity of the larynx and can cause injury to the vocal cords. For these reasons, the manufacturers of all currently available laryngeal surface electrodes do not recommend continuous laryngeal electrode placement for monitoring purposes in excess of eight hours. The surgeon and anesthesiologist are therefore required to remove the dedicated endotracheal tube with attached electrode and reintubate the patient with a standard, non-electrode endotracheal tube prior to moving the patient to the recovery room or ICU for prolonged respiratory support. This entails the risk of a separate, second airway manipulation and

deprives the physician of valuable information which is provided by prolonged and continuous laryngeal monitoring.

Additionally, because the components of the electrodes in current embodiments of attachable or integrated endotracheal tube electrodes are different in structure and type to standard endotracheal tube components, they create a zone of stiffness that does not allow, or retards, flexing of the endotracheal tube when placed in its desired position, namely in a semi S-curve configuration extending for the length of the electrode element. By constructing the part of the endotracheal tube electrode that is inside the patient's mouth, pharynx, and larynx using components which are flexible, rather than rigid, such as described herein below, the endotracheal tube electrode are located for optimal signal collection and minimal negative effects on the surrounding laryngeal tissue, subject to other constraints caused by the other materials used to form the laryngeal tube.

SUMMARY

An device for prolonged laryngeal electromyography monitoring comprises, in a preferred embodiment, an endotracheal tube, which can be a standard commercial endotracheal tube, with electrodes and electroleads screen printed on the exterior surface thereof using a conductive ink or paint, in a pattern such that it is optimized for positioning in the larynx and collection of electrical signals from the muscles and nerves comprising the vocal cords. The current most commonly used endotracheal tube is made of polyvinylchloride (PVC) or Silastic™. These tubes may also be imprinted with lettering to designate the manufacturer, size, serial number, scaled length to indicate depth of penetration from the lips, and other written precautions and information such that the manufacturer and regulatory agencies deem appropriate. As such the endotracheal tube laryngeal surface electrode incorporates imprinted patterns which provide conductive electrode plates on the surface without adding any additional structure or materials to the standard endotracheal tube other than the conductive ink or materials applied to the surface to form the electrodes. In a first embodiment the conductive paint or printing ink used consists of a liquid solution or suspension of conductive material, such as a silver, gold, silver chloride, or various other conductive materials, such that when the solution dries or otherwise solidifies it forms a firmly adherent, thin, electrically conductive layer on the body of the tube. In an alternative embodiment, the conductive material may be sprayed on the tube surface in the desired pattern to form continuous conductive patterns on the surface.

An object is to provide a laryngeal surface electrode on an endotracheal tube where the electrode plates do not raise the profile of the body of the tube so as to create a safety hazard from possible trauma to the vocal cords.

Another object is to provide a laryngeal surface electrode that can be used for prolonged intubation and prolonged contact of the electrode surfaces with the vocal cords without raising concerns of unsafe condition or traumatic injury to the vocal cords resulting from separation or delamination of the electrode structure from the endotracheal tube surface.

Another object is to provide a laryngeal surface electrode that can remain indwelling during the entire surgical procedure and intensive care period of treatment of the patient, thereby providing the medical practitioner the ability to review laryngeal electromyography monitoring to assess the depth of sedation during treatment or surgery allowing the assessment of the patient's laryngeal motor power during the decision process leading to removal of respiratory support and of the endotracheal tube.

An additional object is to provide a PVC laryngeal surface electrode with the electrodes painted, printed or sprayed on the surface thereof, thereby providing the flexibility of the PVC material throughout the length of the device. The painted, printed or sprayed on electrodes does not create a zone of stiffness anywhere along the length of the endotracheal tube, and particularly near the vocal cords. The flexibility of the endotracheal tube is not constrained or otherwise compromised by incorporation of a separate electrode structure on the tube surface. In addition, the traces, also referred to as leads are likewise applied to the surface of the tube, allowing the lead wires to be attached near the top of the tube (the external end of the endotracheal tube), and outside the patient's mouth, thus eliminating additional clutter in the patient's pharynx and an additional possible source of injury to the vocal cords with malpositioning of the device.

An additional object is to provide a laryngeal surface electrode that can be manufactured with electrode surfaces and multiple electrodes for various different applications and endotracheal tube sizes so as to provide a dual channel structure with four electrode plates or pediatric (single electrode) versions.

A further object is to provide an electrode that is economical to manufacture, efficient to use, and particularly well adapted for prolonged use. Other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a part of this specification and include exemplary embodiments and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 2 is a bottom view of the embodiment of FIG. 1.

FIG. 3 is a cross sectional view of the embodiment of FIG. 2 taken along line 3-3 of FIG. 2.

FIG. 4 is a perspective view of a second embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 5 is a top view of the embodiment of FIG. 4.

FIG. 6 is a view showing the endotracheal tube of FIG. 4 placed within the trachea with the electrode plates adjacent the vocal cords.

FIG. 7 is a perspective view of a further embodiment of an electrode for prolonged monitoring of laryngeal electromyography incorporating features of the invention.

FIG. 8 is a view showing the endotracheal tube of FIG. 7 placed within the trachea with one electrode plate adjacent the vocal cords and one electrode contacting the tongue.

DETAILED DESCRIPTION

Certain features of the device described and shown herein are enlarged in the Figures for clarity and may be smaller and thinner than depicted in the Figures. In addition, other components, which may or may not be transparent, are shown as transparent so that the locations of the underlying features are readily visible.

With reference to FIGS. 1-3, a laryngeal electromyography tube 10 for use in prolonged laryngeal electromyography monitoring is shown. The laryngeal electromyography tube 10 comprises an endotracheal tube 12 upon which conductive

electrode plates 14 are imprinted on the linear body of the tube 12 from a point adjacent to the endotracheal tube balloon 15, shown as a transparent material, at the distal end 16 of the tube 12. The length of the electrode plate 14 is chosen so as to be appropriate for clinical use and electrical signal capture. Extending away from the plates 14, toward the proximal end 18 of the laryngeal electromyography tube 10 is a conductive trace 20 which terminates on a conductive pad 22 for attachment of a lead wire 24. The lead wire 24 is of a length suitable to allow the laryngeal electromyography tube 10 to be attached to externally located electro-physiologic devices (not shown) such that the user may capture and evaluate the signals from the vocal cord received by the plates 14.

A typical endotracheal tube has a curved shape, such as an arc as shown in FIGS. 1-3 which typically is bent into an S-shape to match the anatomy of the throat. In FIGS. 1-3 the printed electrodes are shown on the outer curved surface for receiving electrical signals generated from nerves and muscles in the rear of the trachea. A second embodiment of the laryngeal electromyography tube 40 shown in FIGS. 4 and 5 has the electrodes placed on the concave (inner surface of the curve) for picking up signals generated from the vocal cord located on the front surface of the trachea. FIG. 6 shows a third embodiment of a laryngeal electromyography tube 50 incorporating features of the invention. This embodiment incorporates the electrode plate 14 placement of FIGS. 1-3 with the conductive trace 20 running along the lower surface of the endotracheal tube, the portion of the trace 20 connecting to the plate 14 curving around the surface of the endotracheal tube so that the electrode plate 14 faces rearward to contact the vocal cords and the conductive trace 20 is on the lower surface of the tube as it passes through the mouth (i.e., facing the tongue). One skilled in the art will recognize that other electrode placements may be desired and it may in fact be desirable to have electrodes extending further around the circumference or even around the full 360° circumference of the tracheal tube.

Additional imprinting 26 for informational purposes is applied using nonconductive paint or printing ink is also seen on the body of the invention. An insulating covering 28, shown as a transparent material, is applied over the traces to protect against electrical shorting.

FIGS. 7 and 8 show a still further embodiment 60 which includes a single wide electrode 62 in contact with the vocal cords and a second electrode 64 which rests against the tongue as best shown in FIG. 8. In FIG. 7, a second conductive pad 22 connected to the trace 66 is not seen as it is on the backside of the endotracheal tube as viewed in FIG. 7.

A suitable conductive composition, referred to as an ink or paint, for forming the plates 14 and the traces 20 comprises a mixture of conductive materials, preferably metallic particles or metallic salts or oxides dissolved or suspended in a liquid carrier. Suitable conductive particles include, but are not limited to, finely divided particles or flakes of silver, silver salts such as silver chloride, silver oxide, gold, copper, copper chloride, copper, platinum, carbon or graphite. The conductive materials are provided in the form of pellers, flakes, and nanoparticles. Silver is preferred because it is highly conductive (it has a resistivity of $1.62 \times 10^{-8} \Omega m$), is oxidatively stable and has the added advantage that its oxide is electrically conductive. Copper has a similar resistivity but its oxide acts as an insulator. The conductive materials are dissolved or suspended in a carrier which can be readily evaporated, leaving the conductive particles adhered to the surface of the endotracheal tube and in contact with adjacent particles to create a continuous conductive path from the electrode plate 14 along the length of the endotracheal tube to the conductive

pad 22 and then to the lead wires 24. A typical ink comprises a mixture of the conductive material, which may include one or more different materials such as silver in combination with silver chloride, in a liquid carrier, and may also include a binding agent or adhesion promoter. A typical ink for use on a polyvinyl chloride (PVC) endotracheal tube comprises 20-40% of a liquid carrier and 60-80% of a conductive material blend. For example a particular embodiment for use on PVC comprises 30% of a liquid carrier, such as dipropylene glycol methyl ether, 60% silver in the form of 50% silver flakes and 10% silver chloride, and a resin binder such as a modified polyester resin. Once the liquid carrier is removed, the printed electrode comprises about 85% conductive silver material (silver and silver chloride), the balance being the resin binder. Numerous suitable conductive inks are available from Creative Materials of Tyngsboro, Mass.

For use on a silicone endotracheal tube a preferred carrier liquid is Xylene. The ink typically has a viscosity in excess of 10,000 centipoises, preferably about 12,000-16,000 cps. One skilled in the art will recognize that numerous different carriers can be employed, preferably a liquid that does not attack or dissolve the polymeric material comprising the endotracheal tube and is readily evaporated. For example, other suitable liquid carriers include water, methanol, ethanol, isopropanol, 1-methoxypropanol, butanol, ethylhexyl alcohol, terpineol, ethylene glycol, glycerine, ethyl acetate, butyl acetate, methoxypropyl acetate, carbitol acetate, ethylcarbitol acetate, methylcellosolve, butylcellosolve, diethyl ether, tetrahydrofuran, dioxane, methyl ethyl ketone, acetone, dimethylformamide, 1-methyl-2-pyrrolidone, hexane, heptane, dodecane, paraffin oil, mineral spirit, benzene, toluene, xylene, chloroform, methylene chloride, carbon tetrachloride, acetonitrile and dimethylsulfoxide. The viscosity should also be such that the ink once applied does not flow on the surface of the tube so that the dimensions of the printed or painted electrode can be held with design parameters as to with ands thickness.

To apply the ink to the endotracheal tube the tube can first be wiped with a solvent to remove any oils or foreign materials on the surface. Care must be taken to select a cleaning solvent that is compatible with the polymeric material comprising the endotracheal tube and does not affect the surface of the tube. However, wiping the surface may not be necessary. In a first embodiment the conductive ink is applied using a brush, preferably in an automated manner to assure reproducibility. However, other techniques can be utilized such as spraying or using a roller type applicator or other typical printing techniques. In a preferred embodiment the printed surface is subjected to an elevated temperature (35° C.-140° C.), preferably 100° C.-140° C. for several minutes to quickly 40 evaporate the liquid carrier followed by 12-24 hours exposure in clean environment at ambient temperature. The resultant device is an endotracheal tube with an electrode structure toward the distal end thereof and traces from the electrode structure to the proximal end permanently printed on the outer surface thereof, the traces being electrically insulated. The printed electrode and traces are about 0.001 inches (25 microns) in thickness so that the diameter of the endotracheal tube is substantially unchanged and there are no extraneous intervening materials, such as is present when a stick-on 45 electrode is used, which can lift up or present sharp edges.

A PVC endotracheal tube incorporating an electrode structure painted on the surface in the manner described above using the silver/silver chloride ink described above has been used in patients and provides consistent stimulation delivery (the average minimum current required for stimulation of the RLN is about 0.50 mA) and a measurably and consistent

output comparable to current electrodes adhesively secured on endotracheal tubes, such as the Dragonfly® stick-on laryngeal electrode supplied by Neurovision Medical, Inc.

Such a composition can be applied by various methods including but not limited to painting, screen printing, transfer printing, gravure, flexographic or offset printing, as well as inkjet or electrostatic printing methods. The conductive solutions preferably use rapidly evaporating solvents which may be provided with high concentrations of the conductive component and can in fact be provided as a solvent free composition. As an alternative, a polymer doped with conductive additives can be used. In a still further embodiment electrically conductive polymers can be used. Based on the teachings herein one skilled in the art will recognize that other conductive solutions or compositions can be utilized.

Preferred materials for construction of the endotracheal tube are PVC or a silicone polymer, such as Silastic®. However, based on the teachings herein one skilled in the art will recognize that numerous alternative materials may be used to construct the endotracheal tube 12. The non-conductive, insulating covering 28 is chosen to be compatible with the tube 12 material to minimize or eliminate the likelihood of delamination. For example, on a PVC endotrachcal tube a PVC insulating covering 28 is preferred. For a silicone endotracheal tube, a silicone insulating covering 28 is preferred. While the device described herein is an endotracheal tube, one skilled in the art will also recognize that other medical devices, such as catheters can be prepared in the same manner to have electrodes on the surface thereof.

The endotracheal tube with imprinted electrode surfaces allows safe, long term intubation and clinical monitoring of human laryngeal electromyographic signals without detrimental reduction in the quality of the electrical signal or injury to the trachea. Prior and currently available devices include structures on the surface of the tube which are raised and can have sharp edges and which can cause injury to the tissue of the throat, larynx and vocal cords. For these reasons, the manufacturers of all currently available laryngeal surface electrodes do not recommend continuous laryngeal electrode placement for monitoring purposes in excess of eight hours. The surgeon and anesthesiologist are therefore required to remove the dedicated endotracheal tube with attached electrode and reintubate the patient with a standard, non-electrode endotracheal tube prior to moving the patient to the recovery room or ICU for prolonged respiratory support. This entails the risk of a separate, second airway manipulation and deprives the physician of valuable information which is provided by prolonged and continuous laryngeal monitoring. Since the currently described device with electrical paths applied directly to the surface of the endotracheal tube are smooth, these hazards are eliminated. The described device can be placed prior to or at the time of the surgical procedure, and it can remain in position in the patient after the procedure (i.e., in the recovery room, ICU and subsequent prolonged respiratory support) with significantly reduced risks of injury to the patient. Intubations in excess of 8 hours and in fact for 24-48 hours (long term intubation) are therefore now possible.

Further, printing the electrode on the surface provides for optimization of the configuration of the electrode plates on the body of the endotracheal tube without introducing stiff attachments or physical additions. As a result no physical stress is placed on the tube that could inhibit easy placement of the tube in the trachea of a human patient.

While specific embodiments are disclosed herein, it is understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various forms.

Specific structural and functional details described herein are not to be interpreted as limiting, but merely exemplary and are a basis for teaching one skilled in the art to practice the invention claimed herein below.

The invention claimed is:

1. A device for use in monitoring electrical signals during laryngeal electromyography comprising:
 - an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface first and second electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of said electrically conductive electrodes positioned to contact the vocal cords, the second electrode positioned to contact tissue, nerves and muscle in the trachea or the tongue when the tube is positioned in the trachea,
 - said tube having on its surface first and second electrically conductive traces, said traces electrically isolated from each other, each trace connected to or integral with an electrode, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal portion of the tube,
 - a proximal connection point connected to or integral with each of the conductive traces, the connection points applied directly to the tube surface at a proximal end of the traces on the endotracheal tube, and
 - electrical leads connected to the connection points, said leads adapted for connection to monitoring equipment, the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrodes to a point adjacent the connection points.
2. The device of claim 1 wherein said electrically conductive electrodes, traces and connection points comprise a dry conductive paint or printing ink.
3. The device of claims 1 wherein the surface of the conductive electrodes are substantially flush with the outer surface of the endotracheal tube.
4. A method of forming an electrode bearing endotracheal tube for laryngeal electromyography comprising:
 - providing an endotracheal tube having a retaining balloon at a distal end thereof,
 - forming first and second electrodes on an exterior surface of the endotracheal tube, a first of one or more electrically conductive traces attached to the first electrodes and a second of one or more electrically conductive traces attached to the second electrodes, first and second connection points at a proximal end of the first and second traces, the first and second electrodes located proximal of the retaining balloon, the connection points located at the proximal end of the traces,
 - the electrodes, traces and connection points formed by applying a conductive ink or paint to the exterior surface of the endotracheal tube, and
 - forming an electrically insulating barrier over the traces, the barrier extending from a point of connection of the traces to the electrodes to the connection points on the proximal end of the traces.
5. The method of claim 4 wherein the first electrodes positioned to contact the vocal cords and the second electrodes positioned to contact the tongue or nerves and muscle in the rear of the trachea when properly positioned for performing laryngeal electromyography.

6. The method of claim 4 wherein the conductive ink or paint comprises electrically conductive particles in a liquid carrier.

7. The method of claim 6 wherein electrically conductive particles comprise finely divided particles or flakes of elemental silver, silver salts, silver oxide, gold, copper, copper chloride, platinum, carbon or graphite.

8. The method of claim 7 wherein the silver salt is silver chloride.

9. The method of claim 6 wherein the conductive particles comprises at least about 60% of the ink.

10. A method of conducting monitoring of electrical signals during laryngeal electromyography for a period of time in excess of 8 hours without injury to the trachea comprising:

- providing an endotracheal tube having a retention balloon at or adjacent a distal end thereof,
- forming on the outer surface of said tube

a) one or more electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes,

b) electrically conductive traces connected to or integral with the electrodes, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal portion thereof,

c) connection points connected to or integral with the conductive traces applied directly to the tube surface at a proximal end of the traces, and

d) electrical leads attached to the connection points, said leads adapted for connection to monitoring equipment,

e) the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrodes to a point adjacent the proximal ends of the traces,

wherein said electrically conductive electrodes, traces and connection points comprise a conductive paint or printing ink,

placing the endotracheal tube in the trachea with at least one electrode in contact with the vocal cords, and monitoring electrical signals with the at least one electrode, said monitored electrical signals not showing a detrimental reduction in the quality thereof during the period of monitoring.

11. The method of claim 10 wherein the period of monitoring exceeds 24 hours.

12. The method of claim 10 wherein when a first electrode is placed proximal of the balloon and positioned to contact the vocal cords a second electrode is positioned so as to contact tissue, nerves and muscle in the rear of the trachea or the tongue.

13. The method of claim 12 wherein the period of monitoring exceeds 24 hours.

14. A device for use in monitoring electrical signals during laryngeal electromyography comprising:

- an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface at least first and second electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of the first or second electrodes positioned to contact the vocal cords, a wall of the trachea or the tongue when the tube is positioned for electromyography in the trachea with the retention balloon distal of the vocal cords,

said tube having on its surface first and second electrically conductive traces, said first trace connected to or integral with the first electrode and said second trace integral with the second electrode, the traces applied directly to the tube surface, electrically isolated from each other, and running along the length of the endotracheal tube to a proximal portion thereof, and
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electrical leads connected to the electrically conductive traces or to conductive pads connected to or integral with the conductive traces, said leads configured to connect to monitoring equipment.

the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode to which it is attached to a point adjacent the electrical leads or the conductive pads.

15. The device of claim 14 wherein said electrically conductive electrodes and traces comprise a conductive paint or ink.

16. The device of claim 15 wherein the conductive paint or ink is a dried conductive paint or printing ink free of a liquid carrier.

17. The device of claims 14 wherein the surface of the conductive electrodes are substantially flush with the outer surface of the endotracheal tube.

18. The device of claim 14 wherein said first electrode is 25 located a predetermined distance proximal of the balloon and positioned to contact the vocal cords, said second electrode electrically isolated from the first electrode and located at said same predetermined distance or further proximal thereof.

19. The device of claim 14 wherein said first electrode is on 30 a posterior surface of the endotracheal tube and said second electrode is anterior thereto.

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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF VENTURA

I am employed in the County of Ventura, State of California. I am over the age of 18 and not a party to the within action. My business address is 300 Esplanade Drive, Ste. 850, Oxnard, California 93031.

On November 12, 2014, I served the foregoing document(s) described as **CIVIL PROCEDURE CODE § 2019.210 DISCLOSURE** on the interested parties in this action, by placing the original X a true copy thereof enclosed in a sealed envelope addressed as follows:

John S. Kyle, Esq.
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X (BY FIRST CLASS MAIL) (BY EXPRESS MAIL) I caused such envelope with postage thereon fully prepared to be placed in the United States mail at Ventura, California. I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. It is deposited with the U.S. Postal Service on that same day in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date of deposit for mailing in affidavit.

X (State) I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on November 12, 2014, at Oxnard, California.

SUSAN E. MONTORIO